IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Kohl, et al.	Art Unit	: 1625
Patent No.	: 7,470,791	Examiner	: Z.N. Davis
Issue Date	: December 30, 2008	Conf. No.	: 2320
Serial No.	: 10/531,720		
Filed	: April 18, 2005		
Title	: NOVEL PROCESS FOR THE PREPARATION OF ROFLUMILAST		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR RECONSIDERATION OF PETITION UNDER 37 C.F.R. § 1.183 AND, ALTERNATIVELY, PETITION UNDER 37 C.F.R. § 1.181

In the Decision dated September 17, 2010 ("the Decision"), the United States Patent and Trademark Office ("the Office") dismissed Patentees' Petition under 37 C.F.R. § 1.183 ("the Petition") and Application for Patent Term Adjustment. The Petition was styled as a "Reply to Dismissal of Request for Recalculation of Patent Term Adjustment in view of Wyeth", but treated by the Decision as a "petition under 37 C.F.R. § 1.183, requesting suspension of the time limit for consideration of a request for reconsideration of a patent term adjustment (PTA)".

The Petition had requested reconsideration of the patent term adjustment calculation according to the rule established by the court in Wyeth v. Dudas, 580 F. Supp. 2d 138 (D.D.C. 2008). By the Decision, the Office has refused to suspend the time limit and, as a result of that refusal, dismissed the Application for Patent Term Adjustment as untimely filed. Because the Office did not consider the merits of the Application for Patent Term Adjustment, the only issue presented in this request for reconsideration is the Office's dismissal of the Petition.

The Office had published in the Federal Register (in 2004) an interpretation of the statute governing patent term adjustment that unambiguously supported the Office's final patent term adjustment calculation for U.S. Patent No. 7,470,791 ("the patent"). In reliance on the Office's presumed ability to publish an interpretation that is not inconsistent with the statute, Patentees did not challenge the Office's patent term adjustment calculation within two months after grant of the patent. However, on September 30, 2008, the U.S. District Court for the District of

Columbia issued the opinion in Wyeth v. Dudas finding that the Office's interpretation of the patent term adjustment statute is in error.

37 C.F.R. §1.183 provides that "[i]n an extraordinary situation, when justice requires, any requirement of the regulations in this part which is not a requirement of the statutes may be suspended or waived ..." The time period specified under 37 C.F.R. § 1.705(d) is not a requirement of the statutes and is therefore eligible for suspension under 37 C.F.R. §1.183. The Office has not disputed that it is within the Director's authority to waive the two-month requirement. However, despite having such authority, the Office declined to grant such a waiver in this case. Thus, as noted in the Petition, this has "left the Patent Owner with a right to seek corrected PTA but without a remedy for obtaining that correction of PTA."

The Decision notes that the February 1, 2010 Federal Register Notice, provided a "limited waiver" of the two month deadline for filing a petition for reconsideration of a PTA determination under 37 C.F.R. § 1.705(d).

The present case presents a rare instance where the Office's published interpretation of a statute has been overturned by a court. Patentees are unaware of a single previous instance where a court has rejected a published interpretation of the patent term adjustment statute made by the Office. Such a unique occurrence qualifies as an "extraordinary situation."

Patentees should be able to rely on the Office's ability to draft and apply regulations that are not inconsistent with the statute. The Office has particularized expertise and should be given wide latitude when taking on the important task of promulgating regulations and written interpretations of the statute. This is not merely a matter of an individual Examiner or a Board issuing a final decision, which decision is subsequently challenged and reversed by a court. This is a rare instance where the Office has put its full authority behind a published interpretation that has later been rejected by a federal court. In such an exceptional case, it would be manifestly unjust to punish those patentees who made an earnest attempt to comply with the laws and regulations as interpreted by the Office.

The Office's erroneous written interpretation of the law is the primary reason why Patentees do not currently enjoy the full patent term adjustment to which they are legally

entitled. The Office's contribution to the Patentees' predicament is highly relevant in determining whether justice requires invocation of the Director's authority under 37 C.F.R. §1.183. See Helfgott & Karas, P.C. v. Dickenson, 209 F.3d 1328 (Fed. Cir. 2000). In Helfgott, the Office had refused to grant a petition under 37 C.F.R. §1.183 to permit an applicant to correct an erroneous filing that had been made in a PCT application. Id. at 1329-33. The court held that the Office's refusal to grant applicant's requested relief via a 37 C.F.R. §1.183 petition constituted an abuse of discretion under the Administrative Procedure Act. Id. at 1337. "[T]he argument for the exercise of discretion would appear to be especially strong in this case, where the harmful actions of the PTO were, as noted above, in contravention of the PCT Guidelines, which requires that the applicant be given notice whenever documents filed with the PTO are altered." Id. In Helfgott, the Office's misapplication of a PCT rule made it "a primary contributor" to the applicant's subsequent loss of legal rights. Id. at 1335. Similarly, in this instance the Office's publication of an incorrect legal standard was the primary cause of Patentees' potential loss of legal rights. When the Office takes the significant step of publishing in the Federal Register an interpretation of a statute that is later held to be incorrect, justice requires that the Office take those remedial steps that are within its authority to undo the damage that it has caused.

Wyeth was not the only instance where the Office had followed a practice that was later found to deny some patentees the full patent term adjustment to which they are entitled under the law. In 2004, without court intervention, the Office amended the rules governing patent term adjustment to modify its previously overly-stringent interpretation of what can be considered a "decision" within the meaning of 35 USC 154(b)(1)(A)(iii).[1] In view of its change in statutory interpretation, and the obvious unfairness to patentees that had suffered loss of rights by not contesting the Office's narrow interpretation of the statute within two months after patent issuance, the Office provided a time period in which patentees whose patent term would have

[1] The Office reversed its position that a remand from the Board of Patent Appeals and Interferences could not be a "decision" as that term is used in 35 USC 154(b)(1)(A)(iii).

been calculated differently could file a request for reconsideration under the revised rule.[2] The Office's position that it "believes that the 180-day period in 35 U.S.C. 154(b)(4) represents the outer limit on the USPTO's ability to consider a patentee's initial request for PTA determination {to conclude its PTA determination}" (Decision at 2) is irreconcilable with the Office's previous provision of a remedy for all patentees (*including those whose patents had issued more than 180 days earlier*) following a different change in the Office's application of the patent term adjustment statute. It would be arbitrary and capricious and an abuse of discretion for the Office to have provided a retroactive remedy for the previous Office error but not to do so for the Office error that is the subject of the Petition. There is no rational basis to select one class of systemic patent term adjustment errors as deserving of a retroactive cure while denying a retroactive cure to another class of systemic errors.

As detailed in the application for patent term adjustment enclosed with the Petition, the patent will have a term that is shorter than that to which it is legally entitled if the Petition is not granted, seriously prejudicing Patentees in fully enforcing their statutory patent rights. In view of Patentees' detrimental reliance on the Office's published interpretation of the patent term adjustment statute and regulations, and in the interests of fundamental fairness, Patentees respectfully request that the time limit for consideration of an application for patent term adjustment be suspended so as to permit reconsideration according to the rule established by the court in Wyeth v. Dudas.

The Decision did not include a specific time period for seeking reconsideration. This Request is submitted within 1 month of the mailing date of the Decision. In the event that no period for response was intended, Patentee petitions in the alternative under Rule 181(3) to invoke the supervisory authority of the Director to consider the request set forth in this petition.

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[2] "Revision of Patent Term Extension and Patent Term Adjustment Provisions" published on April 22, 2004 at 69 Fed. Reg. 21704-11.

No fee is believed due. However, if any fee is due, please charge it to Deposit Account No. 06-1050, referencing Attorney Docket Number 29296-0003US1.

Respectfully submitted,

Date: Oct 18, 2010

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